



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFA-305

MAR 8 2000 8 6 3 '00 MAR 13 11:15

Food and Drug Administration
Rockville MD 20857

Ms. Wendy Berkowitz
39 Pleasant Ave.
Passaic, NJ 07055

Dear Ms. Berkowitz:

This is in response to your letter dated February 14, 2000, concerning the use of recombinant Bovine Growth Hormone (rBGH) in dairy cows.

Thank you for sharing your concerns on this issue. The use of drugs in livestock and poultry is strictly regulated. Before any drug intended for use in animals is approved, it must undergo extensive chemical and toxicological testing which must demonstrate that the food from these animals is safe for human consumption.

Bovine somatotropin (bST) was approved by the Food and Drug Administration (FDA) in 1993. The recombinant, or genetically engineered form of bST (rbST) is virtually identical to a cow's natural somatotropin, a hormone produced in its own pituitary gland that stimulates milk production. Since bST is a protein-based hormone, rbST is broken down during digestion, which makes it biologically inactive and incapable of having any effect in humans or animals. Over 120 studies were reviewed by FDA scientists that examined the safety of milk and meat from dairy cows treated with rbST. They concluded that there was no increased health risk to consumers.

I am enclosing materials that provide further information concerning this matter. In addition, I am forwarding your letter to Dockets Management Branch for inclusion in Docket Number 98P-1194 -- Withdrawal of NADA Approval for Posilac -- rBGH. Please visit our Internet Home Page at <http://www.fda.gov/cvm>.

Sincerely yours,

Karen A. Kandra
Karen A. Kandra
Consumer Safety Officer
Center for Veterinary Medicine

Enclosures

98P-1194

C771/HN3

Drug Administration 28P
5600 Fishers
Rockville MD 20857 Feb. 14, 2000
Dear Sirs/Madams:

I am writing about Bovine Growth Hormone. I am surprised that, given all we don't know about it, + given the negative things we do know about its effect on human health, the US FDA approved it. This should never have been approved.

I am writing to urge you to take BGH off the market + outlaw its use. If you are not prepared to do that at this time, at least require labelling of all products that are made from cows treated with Bovine Growth Hormone.

Please Reply. I'd like to be kept informed about the FDA's actions regarding BGH and all genetically-engineered products.

Thank you

Wendy Berkowitz
Wendy Berkowitz
39 Pleasant Avenue
Passaic NJ 07055

FDA-00-1463

39 Pleasant Avenue
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Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857

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